The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Sanofi is notifying healthcare professionals about a recall of one lot (# EY0330) of ALTUVIIIO [antihemophilic factor (recombinant), Fc-VWF-XTEN] after it came to our attention that the label contains erroneous text regarding product dose potency.

ALTUVIIIO lot #EY0330 of 2000 IU nominal vial potency was erroneously labelled with an actual potency of 2132 IU/mg on the finished product and cartons, instead of the correct value of 1811 IU/vial. The nominal value of 2000 IU/vial is correct and the actual potency is still within FDA-approved manufacturing specifications.

The dose of ALTUVIIIO lot #EY0330 is consistent with the recommended dosing in the USPI and is not expected to have a clinical impact on patients who are on a prophylactic regimen, as the FVIII activity levels should remain in the protective range to prevent spontaneous bleeding.

PRODUCT: ALTUVIIIO [antihemophilic factor (recombinant), Fc-VWF-XTEN]

NDC NUMBER: 71104-982-01

LOT NUMBER: EY0330

EXPIRATION DATE: 10/2027